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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,977	12/12/2001	Kin-Ping Wong	AN 2002.00	4934

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COE, SUSAN D

ART UNIT	PAPER NUMBER
1654	8

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,977	WONG, KIN-PING	
	Examiner Susan Coe	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 November 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 7-18 and 21 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6, 19, and 20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-21 are currently pending.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-6 and 19-21, and cancer for species A in Paper No. 7, dated November 18, 2002 is acknowledged. The traversal is on the ground(s) that the composition is not used for a materially different process because the cited example of "improving blood circulation" is related to the claimed methods of use. However, it is unclear how the improvement of blood circulation is related to all of the numerous disorders claimed by applicant. In addition, the composition could be used as an anti-viral agent which would not have relation to many of the claimed disorders.

Applicant also argues that it would not be burdensome to search the entire invention because they are classified in the same class and subclass. However, while a search of the patent literature might overlap to some extent, it would not necessarily be coextensive especially in regards to the search of the journal literature that is required to thoroughly search a case of this type.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 7-18 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
4. Claims 1-6, 19, and 20 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is indefinite because the extraction process is unclear. It is unclear how many extractions are required to yield ASB03. It is not clear if a first fraction is extracted with an organic solvent to yield ASB03 or if the whole plant itself is extracted with an organic solvent to yield ASB03.

6. Claim 3 is indefinite because the wording of steps a, b, and e are confusing in regards to the antecedent basis. It would be more clear if steps a, b, and e stated:

- “a) obtaining a liquid extract of *Scutellariae barbatae*; obtaining a supernatant by extracting the liquid extract at least two times with ethanol;
- b) obtaining a concentrated supernatant by extracting the supernatant at least three times with methanol;...
- e) resuspending the dried extract in a pharmaceutically acceptable carrier to form a solution;”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1, 4, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Chinese Chemical Letters (1996), vol. 7, no. 4, pp. 333-4).

Applicant's claims are drawn to a process for isolating a fraction from *S. barbatae* by extracting in an organic solvent. The fraction has absorbance between 200nm and 500nm.

Wang teaches a fraction from *S. barbatae* that has absorbance at 259 and 221nm. The fraction is isolated by extracting the plant in ethanol. The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

8. Claims 1, 4, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al. (Tianran Chanwu Yanjiu Yu Kaifa (1992), vol. 4, no. 1, pp. 1-5, CAPLUS abstract).

Xu teaches a fraction isolated from *S. barbata* using water and ethanol. Xu does not specifically teach that the fraction has the same absorbance claimed by applicant. However, since the composition of Xu is isolated using the same extraction procedure claimed by applicant, the composition of Xu would inherently have to have the same characteristics of applicant's fraction if applicant's invention functions as claimed.

9. Claims 1, 4-6, 19, and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 200069452 A1.

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WO '452 teaches an anti-tumor fraction from *S. barbatae*. The fraction is extracted using hot water and / or ethanol. WO '452 does not specifically teach that the fraction has the same absorbance claimed by applicant. However, since the composition of WO '452 is isolated using the same extraction procedure claimed by applicant, the composition of WO '452 would inherently have to have the same characteristics of applicant's fraction if applicant's invention functions as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al.

As discussed above, Wang teaches the claimed *S. barbatae* fraction. Wang does not specifically teach administering the fraction with a pharmaceutically acceptable carrier. Wang does teach that the plant itself has medicinal properties; thus, a person of ordinary skill in the art would reasonably expect that the fraction isolated by Wang would have medicinal properties. Therefore, a person of ordinary skill in the art would be motivated to administer the fraction of Wang in combination with a pharmaceutically acceptable carrier.

Wang also does not teach administering the fraction in combination with an anti-angiogenic or immunostimulatory agent. However, these agents are well known to be added to

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pharmaceutical compositions. Therefore, a person of ordinary skill in the art would have been motivated to add these ingredients to the fraction taught by Wang.

11. Claims 1, 2 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al in view of Wang et al.

Xu teaches isolating a fraction from *S. barbata* by extracting first with water and then with ethanol. While Xu does teach using the same solvents as those claimed by applicant, Xu does not specifically teach the filtration and concentrations steps. However, filtering and concentrating extracts between extraction steps is well known in the art. Therefore, a person of ordinary skill in the art would reasonably expect that the product of Xu could be improved by adding filtering and concentration steps. Thus, an artisan of ordinary skill would have been motivated to add filtering and concentration steps to the extraction procedure taught by Xu.

Xu also does not specifically teach administering the fraction with a pharmaceutically acceptable carrier. However, Wang teaches that the plant itself has medicinal properties; thus, a person of ordinary skill in the art would reasonably expect that the fraction isolated by Xu would have medicinal properties. Therefore, a person of ordinary skill in the art would be motivated to administer the fraction of Xu in combination with a pharmaceutically acceptable carrier.

Xu also does not teach administering the fraction in combination with an anti-angiogenic or immunostimulatory agent. However, these agents are well known to be added to pharmaceutical compositions. Therefore, a person of ordinary skill in the art would have been motivated to add these ingredients to the fraction taught by Xu.

12. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 200069452 A1.

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WO '452 teaches isolating a fraction from *S. barbata* by extracting with water and ethanol. While WO '452 does teach using the same solvents as those claimed by applicant, WO '452 does not specifically teach using each solvent sequentially or the filtration and concentrations steps. However, using solvents sequentially and using filtering and concentrating extracts between extraction steps is well known in the art. Therefore, a person of ordinary skill in the art would reasonably expect that the product of WO '452 could be improved by using the solvents sequentially and adding filtering and concentration steps. Thus, an artisan of ordinary skill would have been motivated to use the solvents sequentially and to add filtering and concentration steps to the extraction procedure taught by WO '452.

13. No claims are allowed. However, claim 3 is considered free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
December 12, 2002



LEON B. LANKFORD, JR.
PRIMARY EXAMINER